1.0 INTRODUCTION

The primary mission of Los Alamos National Laboratory is to apply science and engineering capabilities to areas of national security. The mission has expanded from the research, design, and testing of nuclear weapons to include non nuclear defense programs and a broad array of non defense programs. The Laboratory conducts extensive research in energy, nuclear safeguards and security, biomedical science, computational science, environmental protection and cleanup, health sciences, materials science, and other basic sciences.

The Director's Office has identified the following as significant quality-related goals: the satisfaction of evolving customer needs and expectations and the continuous improvement of Laboratory products and services. This translates into the current vision of a customer focused and unified Laboratory through Quality Management. This vision is being conveyed to all employees through the Laboratory's Initiatives and through the Director's Policy on "Quality."

2.0 PURPOSE

The purpose of the program requirements document is to formally establish the Laboratory's Quality Management Plan (QMP). This Plan establishes for the Laboratory a QMP that:

- o Implements the requirements of 10 CFR 830.120, Quality Assurance Rule for Nuclear Facilities.
- o Implements, as a minimum, the requirements of DOE Order 5700.6C, Quality Assurance Order, for all other operations.
- o Promotes quality in accordance with Malcolm Baldrige National Quality Award (MBNQA) Criteria, and formality of operations at all organizational levels.

This plan outlines general requirements, assigns organizational responsibilities, and describes the process for implementing, assessing, and documenting a QA program that is responsive to the QA requirements of the Department of Energy (DOE), specifically 10 CFR 830.120 and DOE Order 5700.6C, and other customers. This plan is also intended to be an element of the Laboratory's efforts to accelerate its vision to be a "Quality Organization."

The Laboratory's Quality program will reinforce the objectives associated with a total quality management system that strives for continuous quality improvement in Laboratory activities in support of operation and research effectiveness. This program will provide the means to achieve a single, integrated approach to quality requirements and will support continuous quality improvement. The *Quality Assurance Guidebook* developed by the Laboratory Quality Assurance Support Group (ESH-14), provides tools to management that support the implementation of this program.

This plan provides the Laboratory with a program that brings operations into compliance with DOE specified requirements while moving us closer to our vision of a "Quality Organization." It builds on the use of the graded approach to ensure that efforts are appropriately placed and to assure level of resources expended are commensurate with the level of risk (either programmatic, operational, or health and safety related) being abated. The graded approach allows for items to be prioritized, exempted, or even deemed not appropriate based on sound, documented, management decision. The graded approach does not mean that nothing will be done. As a general rule, standard business practices will normally be the bottom of the grading scale and will not necessitate special documentation requirements.

3.0 SCOPE

3.1 Staff

This *Quality Management Plan* (QMP) defines the Quality Management Program at the Lab. The QM program applies to all Laboratory organizations and employees, subcontractors, vendors, contract and consulting personnel, students, and others performing work for the Laboratory.

3.2 Organization

The Laboratory organization is shown in attachment 1 to this Quality Management Plan with the functions of the divisions as shown on the chart. The Division Directors report on equal levels to the Director's Office. Supporting the Director's Office and the Division Directors are various offices such as Human Resources where the Laboratory Training and Development Office resides. Audits & Assessments is the independent assessment function for the Laboratory and is responsible for criteria ten of this plan. There are others such as the Government Relations Office and the Public Affairs Office which are self explanatory. The Quality and Planning Program provides the institutional direction for the Laboratory quality improvement efforts. including the tools for facilitating the improvements identified by the Malcol m Baldrige Assessment effort.

The Business Operations Division provides the information via Administrative Policies and Procedures for planning and scheduling activities. It is the responsibility of each Division to accomplish these activities within their own Division.

The Administrative Policies and Procedures are the procedures by which the Laboratory conducts the day to day business. The Laboratory also has Program Requirements Documents (PRD) such as this Quality Management Plan that provide the requirements to the Laboratory for performance-particular activities within specific fields. Subtier to these are implementing procedures for specific activities including Standard Operating Procedures for performance of tasks.

3.3 Exceptions

The QMP is intended to develop a program that is integrated and comprehensive for all Laboratory operations and is also intended to differentiate between "good management practices" that improve the way we do business and those requirements which are mandated to assure "nuclear safety" and thus subject to Price Anderson Amendment Acts' provisions.

Specifically excluded from the requirements of 10 CFR 830.120 are:

(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act.

(b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion Program, as described in Public Law 98-525; or

(c) Activities conducted under the Nuclear Explosives and Weapons Safety Program relating to the prevention of accidental or unauthorized nuclear detonations.

The enforcement provisions of 10 CFR 820 as they relate to 10 CFR 830.120 apply only to activities within nuclear facilities that have an impact on nuclear safety of the workers, the public and the environment. In other words, 10 CFR 830.120 is to be applied to all work within those facilities that affect the safety envelope of the facility that departmental elements and contractors manage, perform and assess.

The application of the requirements may be accomplished by implementing the requirements of other quality related requirements documents such as QC-1, or project specific requirements such as those governing the Yucca Mountain project.

4.0 REQUIREMENTS

The structure and content of this section are based on 10 CFR 830.120.

This QMP, the program requirements document for QM, will be submitted to the DOE Operations Office Manager for approval.

In the event that the Laboratory's QMP changes, the revised document will be submitted annually to the Operations Office Manager for review. The submittal will include the identification of changes, the pages affected, reasons for the changes, and the basis for concluding that the changes meet requirements.

4.1 Program

Within the Laboratory, each organization's written QM program will encompass the key activities and management controls necessary to implement effective QM processes. Each organization must define, plan, and implement a management system which incorporates methods for managing, performing, assessing the work of the organization, and

demonstrating that a system has been or will be implemented. This system should employ a graded approach to the work. This will include descriptions of the organizational structure. The *Quality Assurance Guidebook* provides guidance of the methods for implementing a QM program with forms that instruct line management through the documentation process and relevant attachments. The organizational structure, functional responsibilities, levels of authority, and organizational interfaces must be defined and communicated. Individual organizations are encouraged and supported in their efforts to tailor QM implementation to their own activities.

The Laboratory Quality Assurance Support Group will assist managers in defining and developing QM program requirements so that the level of formality is commensurate with the level of risk. The customer focus on quality values will be communicated to and reinforced throughout the entire work force.

4.2 Personnel Training and Qualification

Laboratory employees will be qualified as necessary to perform assigned work. Sufficient management attention and resources will be applied to training, and qualification to ensure that employees are adequately prepared to achieve the quality required in their assigned work. Procedures to assure that employees are qualified will be developed. Records will be created and maintained to preserve the basis for management judgment. Qualification requirements associated with special processes and certain inspection, test, and assessment activities will be developed and implemented. Personnel performing work requiring special skills or abilities will be qualified before they perform the work. Personnel will be provided ongoing training as appropriate to ensure the standards in job proficiency are met. This training could include quality assurance training and quality improvement training as a method for enhancing performance.

The Training and Development Office is responsible for all Laboratory training and operates in accordance with procedures meeting the requirements of DOE Order 5480.20. All training programs including those performed by other organizations are approved by this office.

4.3 Quality Improvement

To enhance operational performance and reduce process variability, methods will be established to identify, report, correct, and trend conditions adverse to quality. Currently, each operation or organization is responsible for their own non-conformance reporting procedure. As we proceed, (see Note at the end of this paragraph) a formalized procedure will develop that will institutionalize the reporting method. Senior management is responsible for providing overall direction of the improvement program and recognizes that prompt identification and documentation of deficiencies, coupled with the identification and correction of the root causes, are key aspects of quality improvement. Management at all levels will endorse and promote an environment in which all personnel are expected to identify nonconforming items or activities and potential areas for improvement. The Laboratory Quality Assurance Support Group will maintain copies of all nonconformance reports in order

to establish causes for them, thereby helping to prevent recurrence. (Note: A portion of this effort as related to the requirements of 10 CFR 830.122, "Defect Identification" and 10 CFR 830.350 "Reporting Operational Occurrences" will be assumed before the next revision of this procedure by the occurrence reporting group.)

4.4 Documents and Records

Systems and procedures will be established to ensure that documents generated subject to this program are prepared, reviewed, approved, revised, and distributed with appropriate controls to personnel performing the work. Documents requiring formal control will be identified. Documents include, but are not limited to, procedures, standards, instructions, manuals, drawings, computer codes, purchase orders, vendor manuals, design-basis documents, safety analyses and related reports, QM plans, and other documents important to the implementation of the work.

Systems and procedures will be established to ensure that appropriate records are generated, collected, reviewed, approved, properly stored, and legible. Records requiring formal control will be identified. Retention periods will be identified, and records will be indexed for accountability and retrievability. Appropriate guidance must exist to assure physical protection, preservation, and traceability. Computer hardware and software used to maintain, index, store, or access records will be controlled to ensure accountability, reproducibility, and protection from loss.

4.5 Work Processes

Laboratory management, working with program sponsors, will ensure that work activities and processes are planned in advance and that each organization understands its role and the applicable standards and quality requirements. The organization will identify work processes critical to mission accomplishment and document authorities, responsibilities, interfaces, procedures, standards and performance measures for these processes. The calibration of monitoring and data collection equipment (M&DCE) and measuring and test equipment (M&TE) will be controlled as described in the Laboratory's *Calibration Handbook*. The handbook requires that M&TE used as a basis for acceptance or testing be identified by line and technical management and that data objectives, required accuracy, and specific measuring equipment calibration requirements be identified. Required procedures and training will be incorporated into the work plans, and individuals performing the work will be familiar with the tools, work processes, and specific quality requirements. Critical work processes should be tracked and measured. Required inspections or test points will be identified and incorporated within the overall work plan.

Written procedures and standards will be developed to ensure that an auditable trail is maintained for critical items procured or fabricated. Handling, storage, shipping, and packaging requirements will be identified and addressed. Procedures and standards will address unique requirements associated with items that require in-storage maintenance, that

have a limited shelf life, or that pose a particular hazard to the environment, facilities, or personnel.

4.6 Design

Design activities will be governed by graded procedures, as appropriate, to ensure that design standards and technical, safety, regulatory, operational, and maintenance requirements are appropriately incorporated and achieved using sound engineering and scientific principles. Design control requirements for procured design services will be incorporated into procurement and contract specifications. Design interfaces between interacting disciplines and design organizations will be defined relative to responsibilities, design reviews, design-basis exchange between responsible agencies, deliverables, and associated approvals. The overall system will be designed to ensure that documents and records are appropriately generated, controlled, and retained; and to ensure the acceptability of the deliverable. Design verification and validation will be completed by persons other than those who performed the work. This will be done before the approval and implementation of the design.

Design procedures will address design input, development, analysis, validation, and output to ensure that final designs and the resulting systems or facilities meet specified technical requirements, standards, and codes. Design changes, including those made during fabrication or construction, subsequent modifications, and nonconforming items will be subject to design standards and controls consistent with those applied to the original design. The adherence to the program will preclude the use of unverified design data and assure that appropriate verification or qualification testing is completed before design data are used in subsequent activities.

4.7 Procurement

Procedures will be established to document and control the procurement of quality affecting (including safety) items and services. The requesting organization will use established Laboratory guidance for applying quality assurance controls for procurement. Line management will determine in specifications, drawings, and procurement documents the specification/technical requirements and applicable codes, standards, and necessary QM activities associated with a given procurement. Schedule and acceptance requirements will be established by the requester, including any special handling, packaging, shipping, or storage requirements. Suppliers will be evaluated and selected on the basis of specified criteria. Ongoing reviews to determine suppliers' continued ability to provide acceptable items and services will be performed.

Nonconforming items or services will be documented and controlled to preclude use until compliance with the required technical specification/requirements is demonstrated. Deviations from the requester's requirements will be documented, controlled, reviewed, and

approved by the requester. Procured items must meet established requirements and perform as specified.

Information related to supplier qualification activities and cases of supplier fraud will be conveyed to the DOE in accordance with DOE requirements. Appropriate documents and records will be generated and retained to support the overall procurement action and achievement of the specified requirements.

4.8 Inspection and Acceptance Testing

Procedures will be developed to ensure that inspection and testing requirements are identified and activities are conducted and documented at established hold or witness points. This should be done in accordance with criteria derived from approved drawings, specifications, safety analyses, or other technical documents.

Nonconformances will be documented and resolved in accordance with established procedures. When nonconforming items have been reworked, the reworked items will be inspected for conformance to the original requirements. Personnel performing inspections and tests will be trained and qualified in the test procedures and the equipment to be used and will be certified in the appropriate discipline as necessary. Measuring and test equipment (M&TE) used as a basis for acceptance or testing will be identified by line and technical management. M&TE procedures will provide for the unique identification, maintenance, and calibration of instruments to specified standards, ranges, and tolerances appropriate to their use. The specified standards will be traceable to applicable national standards. Calibration sources will be qualified by the Laboratory. Controlled M&TE will be included within a recall system to ensure the calibration interval is not exceeded. Out-of-calibration conditions will be documented and prior use analyzed to evaluate impact on the validity of acquired data and to determine necessary corrective actions.

4.9 Management Assessment

Each organization's management is responsible for performing internal assessments of that organization's management processes. Organizations will use specific management assessment findings to improve product, service, systems, processes, supplier requirements in order to continuously improve the management assessment process. The information acquired during this review and assessment will be combined with other internal and external information to develop a comprehensive perspective on the overall adequacy and effectiveness of the management systems to achieve stated QM objectives. Special attention will be given to methods of improving processes and procedures, and the barriers to achieving QM goals and objectives will be identified and addressed. The goal of the Laboratory's assessment program is improvement in work products and work processes.

4.10 Independent Assessment

The independent assessment is a function of the Audits and Assessments Office (AA). AA is part of the Director's Office and, therefore, is independent of assessed organizations, facilities, and programs.

AA will perform both compliance- and performance-based assessments. Customer expectations, as defined in DOE and Laboratory requirements, will be used as a basis for assessments of organizations, facilities, and environment, safety, and health; quality assurance; maintenance; and safeguards and security programs. Customers may include DOE and Laboratory management, and the assessed organization.

AA assessments will be performed by teams whose members will be independent of the organizations, facilities, and programs they evaluate. In addition, they will be subject matter experts, and trained in assessment techniques. Assessment techniques will include operational reviews (walk-downs), interviews with management and employees, and document reviews.

A long-range schedule for independent assessments will be developed and routinely updated. Frequency of assessments will be dependent on DOE and Laboratory requirements, inherent risk, public sensitivity, accident experience, and lack of current information about an organization, facility, or program. Performance objectives and criteria, developed from applicable requirements, will be used in the planning and assessments.

The assessment responsibilities include the following:

- o Identify significant potential problems and noncompliances.
- o Identify the probable causal factor.
- o Document the results.
- o Make suggestions for improvement.
- o Track results.
- o Verify resolution of problems and noncompliances.

Assessment results will be documented in reports that are distributed to the deputy director of the Laboratory and all affected organizations. This information can then be used by Laboratory management for planning and continuous improvement of processes and functions. Reports will include noteworthy practices, findings, causal factors, recommendations, and observations. Findings will be tracked, and corrective actions will be evaluated for adequacy and verified. Lessons learned will be communicated to other organizations.

Standards and requirements for independent assessments include DOE Orders 10 CFR 830.120; Director's Policies; Program Requirements Document s; Program Element Documents; and the AA-2 “Quality Management Manual.”

5.0 RESPONSIBILITIES

5.1 Director and Deputy Director

The Director’s Office exercises the ultimate authority and responsibility for quality at the Laboratory. The Director defines the vision, focus, and overall goals and objectives and assigns responsibilities so that appropriate supporting programs, plans, and activities are developed and conducted.

5.2 Program/Division Directors

Program/Division Directors exercise broad authority in leading and managing organizational components of the Laboratory.

Specific responsibilities include the following:

- Review, formulate, and recommend quality-related strategies, policies, and program changes.
- Define specific quality-related requirements for programmatic activities within their divisions.
- Direct the implementation of this program within their organizations and ensure that appropriate levels of quality are achieved by those managers and employees performing the work.
- Ensure that the appropriate resources are available for accomplishing quality activities within their directorates.
- Work in close coordination with the Laboratory Quality Assurance Support Group to ensure the design, development, and implementation of appropriate QAM programs within their directorates and to resolve significant QM issues.

5.3 Management

Line management encompasses group leaders, program managers, facility managers, and others identified as technical management authority for a specific program. Included are both support and technical divisions. Management ensures that specific quality requirements of program sponsors and customers are identified and that all personnel under their supervision

are knowledgeable of their responsibilities for satisfying the technical and quality requirements of the program. Management may delegate tasks to contributing individuals or organizations, but management retains overall responsibility.

Specific responsibilities include the following:

- Actively participate in quality-related activities, including recommending specific changes to policy, program, or procedural documents to achieve QM goals.

- Develop and approve QM plans and procedures in conformance with customer requirements and this program requirements document.

- Communicate QM policies and procedures to employees.

- Identify and prepare planning documents that reflect an activity's technical scope.

- Identify and prepare the administrative and technical procedures necessary to implement the QM requirements applicable to the scope of work.

- Conduct technical reviews of project milestones and issue periodic and final reports that address project-related QM issues.

- Work with the responsible individuals in the division and the Laboratory Quality Assurance Support Group to resolve quality concerns and issues.

- Conduct management assessments for their activities as provided in Section 4.9.

- With employees under their supervision, ensure that design requirements specified in Section 4.6 are met.

- Determine specific requirements for employee training and certification.

- Implement procedures to segregate and control nonconforming items and activities to prevent their inadvertent installation, testing, or use and to govern repair or "use-as-is" dispositions.

- Ensure proper evaluation of identified problems and implement appropriate actions consistent with the nature and seriousness of the problem.

- Implement appropriate administrative controls and procedures for the identification, generation, and control of documents and records.

- Identify within each specific procedure or activity the quality records to be retained. Quality records will depend upon the nature of the work performed but will include such records as quality plans and procedures, design, procurement, inspection,

calibration, audit and assessment, deficiency documents, material control, installation, maintenance, testing, modifications, operations, radiological control records, environmental monitoring, radioactive and hazardous waste transportation, and the control and accountability of nuclear materials.

- o Identify formalized inspection and testing requirements for items produced or procured.

5.4 Human Resource/Training and Development Group

- o The Human Resource/Training and Development Group (HR/T&D) shall provide training and educational services to organizations throughout the Laboratory.

- o The Director of the Laboratory Training Office shall provide uniform direction regarding the overall training effort and organizational training plans at the Laboratory, including general standards and requirements for instructional design, instructor qualification, and training documentation.

- o Ongoing training as required to maintain job proficiency relative to quality assurance will be available through the Laboratory Quality Assurance Support Group and HR/T&D.

5.5 Records Management Document Control

- o The Records Management Document Control Program is responsible for the overall direction and management of the Laboratory's documents and records program.

5.6 Business Division

- o The Business Division, with the assistance of the Laboratory Quality Assurance Support Group, shall implement procedures to ensure that the requester's requirements are incorporated into purchase and contract documents. These procedures will address, when necessary, supplier evaluation, selection, source verification, audit and surveillance, performance verification, receipt inspection, and testing to ensure that the final item or service provided meets the requester's requirements.

5.7 All Employees

All employees have the following responsibilities:

- o Ensure that quality is achieved and maintained in their day-to-day work.

- o Understand and implement quality program requirements associated with work activities.

- o Identify and report nonconforming conditions or other problems adverse to quality.

- o Seek, identify, and recommend work methods or procedural changes that would improve quality and efficiency.

- o Review or check their own work to ensure compliance with requirements.

5.8 Laboratory Quality Assurance Support Group (ESH-14)

The Laboratory Quality Assurance Support Group, under the direction of the Division Director for Environment, Safety, and Health is responsible for the overall establishment of this Laboratory-wide QM program. The primary mission is to support management and organizations at all levels in defining the implementing quality-related requirements. The office maintains the Laboratory's QA program as defined in this plan, and the *Quality Assurance Guidebook*, and provides assurance to Laboratory management that the processes and activities necessary for achieving quality are being conducted. Inherent within its authority to achieve and maintain quality throughout the Laboratory are the following responsibilities:

- o Prepare, revise, maintain, and distribute as necessary, this *Quality Management Plan.*

- o Prepare, revise, maintain, and distribute as necessary, the *Quality Assurance Guidebook*.

- o Provide support and assistance in developing the Statements of Applicability and Compliance Status (which may include approval) used to determine the level of quality to be applied to an activity, program, project, or facility and assist in the identification of the appropriate QA requirements.

- o Develop and maintain an information database of Laboratory QM programs.

- o Represent the Laboratory as required on QM policy or QM program issues and act as necessary as the Laboratory liaison with outside agencies on matters related to QM. With the appropriate line organization, review Laboratory responses to external QA audits for consistency with the Laboratory QM program and for adequacy and impact upon the Laboratory.

- o Assist in providing orientation and training to Laboratory personnel performing quality-related activities to facilitate their understanding and awareness of quality requirements.

- Communicate and promote among management and staff an awareness of the benefits of developing and implementing appropriate QM programs.

- Provide support and assistance to the management of divisions, groups, and projects in instituting required quality programs suitable to their needs and serve as a resource in solving or preventing QM-related problems.

- Assemble, maintain, and manage a QA staff to perform the following functions:

  — Train and qualify QA personnel as dictated by individual programmatic needs.

  — Coordinate and maintain QM program documents.

  — Establish and implement quality familiarization training and specific training courses in support of this program and line management.

  — Establish and implement a QM assessment program in support of QA and QM plans.

  — Assist in establishing and implementing procedures to effectively identify and manage QA records.

- Assist and support Quality Assurance personnel, as necessary, working within divisions in their day-to-day support of line or program management. See section 7.2.3.

- Assist in the establishment of qualification and certification programs for QM personnel and personnel operating special processes or conducting special activities.

- Establish methods for the review, tracking, and trending of nonconformance issues, material inspections, vendor surveillance data, and audit findings and will implement a Corrective Action Report system to identify major conditions adverse to quality.

- Promulgate the Laboratory's counterfeit and suspect materials program, including inspection and acceptance testing. The QA Support Group will assist Laboratory line management, and Laboratory contractors in the identification and disposition of counterfeit and suspect materials.

6.0 RESOURCE REQUIREMENTS

All nuclear facilities will be required to have a Quality Assurance staff sufficient to implement the requirements of their Quality Plan. This may require personnel other than QA such as Records Management and Document Control. The Quality Assurance Support Group provides a core staff that is on call for organizations needing short-term assistance in QM program development. Also available is a Nondestructive Test and Examination Level III

Specialist to provide test and examination support. In addition, QA professionals are available on a recharge basis to provide long-term QM program support and maintenance to requesting organizations. Additional resources will be available as needed.

7.0 IMPLEMENTATION

7.1 Graded Approach to Quality

The Laboratory will use a graded approach to determine quality levels for work activities and items. The leveling of activities or items is not meant to imply a ranking or descending level of quality. Instead, it represents a systematic method of assessing Laboratory projects and activities to determine the appropriate, selective application of the QM program commensurate with risk.

When an activity, program, or project is proposed or otherwise presented for authorization, the responsible manager or technical authority will determine the requirements for a QA plan by **utilizing the *Quality Assurance Guidebook.*** The *Quality Assurance Guidebook* contains forms designed to facilitate this determination of 10 CFR 830.120 applicability, compliance status, and a documentation plan that addresses the Order's provisions on an individual basis. The completed forms will provide documentation of management's decisions regarding **grading of the** implementation of the QM criteria provided in the DOE rule.

7.2 Quality Management Plan

An individual QM plan for a specific program or project will be developed by line management in accordance with the criteria of 10 CFR 830.120. Appropriate guidance is provided in the *Quality Assurance Guidebook*. The QM plan should be used as an integrating document, describing the requirements (including special or unique customer requirements) that apply to the work to be performed and the QM program elements that will apply to the program or project. The QM plan should define the scope of work and applicable quality levels, determined by using a graded approach and assign responsibility for implementing the plan, including the development or integration of procedures to accomplish the key activities.

The QM plan will be used as both a management plan and a planning tool. A well-constructed QM plan integrates requirements from DOE rules and orders; applicable codes and standards; and technical, safety, regulatory, and customer requirements. It establishes the applicable processes and responsibilities within a framework that ensures and documents attainment. If existing documented procedures satisfy requirements, they will be appropriately referenced within the QM plan.

The QM plan will include the following:

- The project name and scope of work.

- Applicability of QM criteria, present compliance status, and plans for preparation of additional QM documentation via the DOE suggested compliance matrix. Forms in the *Quality Assurance Guidebook* may suffice for those managers choosing the Guidebook to develop and implement their QM Plans.

- A summary of or reference to the technical, regulatory, or operational requirements and unique customer requirements that apply.

- The identification of other Laboratory and external organizations that will support the activity and implement QM requirements.

- The requirements for readiness reviews.

7.2.1 QM Plan Development

Management will consider the activities of the organization when determining the need for a QM Plan. Cost and schedule considerations will be taken into account (see Section 7.4). Management has primary responsibility and accountability for the development of the QM plan but may be assisted by organizational QM personnel and the Laboratory Quality Assurance Support Group, which will provide QM support. Because some Laboratory organizations are not focused around a single program or project, it may be appropriate to develop a QM plan for the organization or a segment of the organization rather than a program or project.

When required, program participants such as contributing groups, major suppliers, and design/construction contractors will develop and implement QM programs and/or procedures to ensure that the appropriate management controls are applied to work performed for the Laboratory. Such controls will be consistent with the assigned quality levels.

7.2.2 Approvals

After resolution of any outstanding issues within the applicable management chain, the QM plan may be approved by management and the Laboratory Quality Assurance Support Group and distributed. Changes in the QM plan require the approval of those who approved the original plan.

7.2.3 Implementation

Management is responsible for conducting periodic self-assessments to ensure full implementation of the Quality plan.

7.2.4 Quality Assurance Representatives

Each nuclear facility shall have Quality Assurance personnel responsible for the implementation of QM plans within the organization. The responsible personnel verifies the

status of QA plan development and implementation, and assists management in accordance with the responsibilities outlined in Section 5.3. They will verify the status through periodic surveillances and the assessments. This process may be used for non nuclear facilities also.

- The Quality Assurance personnel will:

  — Assist in the development and application of quality concepts and controls in a manner that contributes to the attainment of project quality objectives.

  — Assist line management in developing QA plans and implementing procedures.

  — Review, concur, and assist in the development of inspection and test plans in support of the line management or technical management authority.

  — Coordinate and perform source, receiving, in-process, and final inspections.

  — Coordinate the disposition of nonconformance reports and attendant corrective actions and trending programs.

  — Assist in the implementation of commitment tracking systems related to QM program requirements.

Upon completion of the program or project, the responsible QM party initiates a Project Close-out Record. In those instances when the QM plan was developed specifically for an organization whose activities are continuous, status reports will be used instead of a Project Close-out Record. A status report or Project Close-out Record will address the following issues:

- A review of the overall effectiveness of QM activities and their contribution to program objectives including lessons learned, so that the Laboratory Quality Assurance Support Group and others may improve the program or processes.

- Close-out of all QM commitments including corrective action requests, deficiency notices, and performance reports.

- QM record disposition and final storage, including Laboratory notebooks, final studies, and test reports, based on records management guidance from the CIC Division.

7.3 Readiness Reviews

Readiness reviews will be performed before major events or all major phased transitions, such as design-to-construction, construction-to-startup, and startup of operations, to verify readiness to proceed. These reviews show whether all requirements have been met before operations begin. Reviews will be performed by representatives of the Department of Energy,

the Laboratory Environmental, Safety and Health Division, the Quality Assurance Support Group, and the Laboratory Assessment Office. The QM plan developed for the program or project will set forth the requirement for readiness reviews. Management will identify a requirement for readiness reviews to verify such prerequisites as the following:

- All previous work has been completed and documentation has been reviewed and finalized. When certain elements of work remain open, documentation for the succeeding phase provides for appropriate controls that will ensure satisfactory completion and inspection.

- Adequate test equipment, tools, and special working environments are in place; proposed process changes and their potential impact on quality have been evaluated.

- Required reviews of design documents, documented work instructions, and detailed technical and QM procedures have been accomplished.

- Personnel performing activities affecting quality have received indoctrination and training to achieve and maintain suitable proficiency in their assigned tasks.

7.4 Phased Implementation of the QM Program

This QM program will be implemented in phases. Implementation of this program will be accomplished in accordance with the facility-specific implementation plans contained in appendices 1 through 9 for nuclear facilities currently in operation. Overall Implementation will be based on the following assumptions:

- Customer-mandated QA requirements that are satisfactorily implemented to meet unique customer QM programs may be accepted and used. A typical example is the use of NASA requirements for space exploration programs.

- When different QM standards are applied to specific programs or projects, only the aspects of this program requirements document and the *Quality Assurance Guidebook* that are directly applicable to the standards imposed will be used as a basis for evaluating compliance. If areas of nonconformance are identified, the QM personnel and line or program management or the designated technical management authority will develop a schedule for bringing the program into compliance.

- For nuclear facilities 10 CFR 830.120 is the governing standard. For new nuclear facilities, assessment of the project will be conducted. If it is ascertained that the implemented QM program is not in compliance with the requirements of the

Laboratory's QM program, management will jointly develop a plan and a schedule to bring the project into compliance.

The Laboratory has a number of successful QM programs, with varying degrees of implementation, some of which have been in existence for many years. We have now embarked on a path toward a mature Lab-wide QM program. A program of this nature is expected to take several years to implement, and will have the following characteristics:

- Enhanced QM awareness throughout the Laboratory, demonstrated by QM Awareness Training for all employees.
- Having a mature Quality Forum by which quality problems and solutions may be exchanged between Laboratory personnel.
- Based on a graded approach, management has used appropriate QM tools to determine the level necessary to enhance operations and will implement QM plans, showing where added value is apparent.
- Assessments have been performed in Laboratory organizations to demonstrate the level of QM implementation.
- Feedback loops have been established to show QM effectiveness throughout the Laboratory.

7.5 Conditions for Stop Work

All employees have the responsibility to stop work that is not being performed safely. Stop-work and restart are governed by the Director's policy on formality of operations.

In the event of a major breakdown in a quality system that the Laboratory Quality Assurance Support Group deems significant, the steps detailed in the Director's policy shall be followed.

7.6 Control of the *Quality Management Plan* and *Quality Assurance Guidebook*

The *Quality Assurance Guidebook* is a controlled-distribution document that will be issued as required to support the development and implementation of QM plans in accordance with the guidance contained in Section 7.2. The *Quality Management Plan* and *Quality Assurance Guidebook* will be controlled and distributed with a transmittal form. Upon receipt of the Controlled Document Transmittal form, the recipient will supply the requested information and return the form. Obsolete copies will be destroyed by the recipient or returned to the CIC Division.

Information copies will be made available by the Laboratory Quality Assurance Support Group, will be stamped as information copies only, and will not be updated.

7.7 Changes to the *Quality Management Plan* and *Quality Assurance Guidebook*

The Laboratory Quality Assurance Support Group will maintain the current version of the *Quality Assurance Guidebook*. As the need arises, the document will be revised and revisions distributed. Sufficient time will be allowed for personnel training before implementation of changes is required. Changes may be requested as follows:

1. Forward to the Laboratory Quality Assurance Support Group a copy of the existing text with the proposed change clearly marked and a memorandum explaining the reason for the proposed change.

2. If the Laboratory Quality Assurance Support Group deems the change desirable, it will perform the necessary coordination and submit the change for approval. The change will be incorporated and issued as replacement page(s) to the *Quality Assurance Guidebook*.

8.0 MEASURES OF PERFORMANCE

Performance will be measured by both management and independent assessments against applicable and DOE QM standards and criteria.

9.0 REFERENCES

The following list of reference documents is not intended to be all-inclusive; rather, it represents documents that most directly provide the framework for the Laboratory's QM program. The measures described in the documents listed below have been used in the development of this program requirements document, and the *Quality Assurance Guidebook*:

DOE Order 5700.6C, *Quality Assurance*.

DOE Quality Criteria QC-1, *DOE/ALO Quality Criteria for Nuclear Weapons Production*

DOE Quality Criteria QC-2, *DOE/ALO Quality Criteria for Research, Design, Development, and Associated Test Activities within the Nuclear Weapons Program.*

DOE Order 4700.1, *Project Management System*.

Los Alamos National Laboratory, Director's Policy 110, *Quality*

10.0 ATTACHMENTS

1. Revision Record
2. Implementation Schedules for LANL Nuclear Facilities

Attachment: QMP Revision Record

Los Alamos National Laboratory

Quality Management Plan

Revision Record:	**Revision 1.0**	**October 19, 1994**
	Revision 0	**March 2, 1992**
	LANL PRD110-01.0	**January 4, 1993**

[Approved by Deputy Director Jim Jackson]

Introduction

The enclosed documents are the plans for implementing the requirements of 10 CFR PART 830.120 (the rule) at Los Alamos National Laboratory (LANL). The institutional plan is an adaptation of the previously approved plan for DOE Order 5700.6C, *Quality Assurance.* This plan provides the direction to LANL's nuclear facilities for adhering to the requirements of 10 CFR PART 830.120. Following the institutional plan are plans for each of the currently operating nuclear facilities. Implementation schedules for those facilities that are not yet fully implemented are depicted on the matrix following each plan. If additional funding is required it is so noted on the matrix for that facility.

We feel that compensatory measures other than those facilities noted on the enclosed facility lists are not required to assure the safety of those facilities.

The approved plan for LANL compliance with DOE Order 5700.6C provided for implementation by January of 1995. The Laboratory has therefore taken the position that if the date is met, LANL will be in compliance with the rule, and it is stated on the matrix.

To determine which nuclear facilities require implementation plans, a list was provided by the Albuquerque Field Office dated September 21, 1993. This list included twenty six candidate nuclear facilities. Thirteen of those facilities were listed as being "current". Of these thirteen, nine are presently active. The four which are not active at the present time are: TA-2, Bldg. 0001, Omega West Reactor; all inventory has been removed and the containment drained. TA-41, Bldg. 1, main vault; all inventory is scheduled to be removed in January, 1995. TA-41, Bldg. 0004, Icehouse vault; inventory has been removed. TA-50, Bldg. 0037, Controlled Air Incinerator; this facility requires an Environmental Impact Statement which is at least three years from completion. Subsequent to receiving the list of nuclear facilities dated September, 1993 and submittal of this plan, a new list dated 11/30/94 that included an additional thirty one facilities was received. The plans for those additional facilities is included following the original nine we addressed.

The nine nuclear facilities and their Quality Management Plans are as follows (see enclosed map):

Chemical Metallurgical Research (CMR) Facility [TA-03]. For this facility we are presenting plans that show full implementation of a facility-wide quality plan by November, 1998. It should be noted that many of the organizations within the CMR building have established quality programs. In order to assure the safe operation of this facility two additional QA personnel have currently been assigned. An additional person is expected to be assigned by the end of January. The facility upgrade program is implementing quality programs very rapidly and has adequate controls at this time to assure the safety of their operations. All of the construction related to the upgrade effort is performed by JCI and inspected by their quality assurance personnel. As noted many of the programs have well implemented quality programs including the WIPP activities, the analytical chemistry activities and many of the mechanical operations. This schedule is consistent with the DOE-approved plan for completing the required training for the facility.

Weapons Engineering Tritium Facility (WETF) [TA-16]. This facility will have a fully implemented quality plan by January 1995. We are presenting the existing quality plan which

was developed in 1988. An organizational change was announced October 1, 1994 which combines the tritium operations. The quality plan is in revision due to this reorganization. A copy of the revised plan will be transmitted as soon as available. At this time it is the intent to combine all tritium operations under one quality plan. When that is accomplished WETF, TSTA, and TSFF will all operate under the same quality plan.

Los Alamos Critical Experiment Facility (LACEF) [TA-18]. This facility will have a fully implemented quality plan by June 1995. Completion of the training is the only thing that remains to be done. Personnel who do not have the required training are not allowed to work in safety affecting operations.

Tritium System Test Assembly (TSTA) and Tritium Science & Fab (TSFF) [TA-21]. These facilities have a fully implemented quality plan. The plans have been implemented by ESH-14 personnel for approximately ten years and have been audited extensively. Both facilities are operated by the same group, therefore, the quality plan is the same for both. The implementing procedures may be unique to the respective facilities. The comments received during the review will be incorporated during the current revision process. (see comment for WETF)

Rad Liquid Waste Treat Facility (RLWTF) [TA-50]. This facility is nearly 100 percent implemented with their quality plan. There is some required training that will not be complete until May 1995, at which time they will be fully implemented.

Waste Characterization Reduction and Repackaging Facility (WCRRF) [TA-50]. This facility will have a fully implemented quality plan by December, 1995. This is the date when the required training is scheduled to be completed. Operations prior to full implementation of the quality plan are governed by existing SOPs or for unique situations, SOPs or work plans are developed.

Low Level Waste Facility (Area G) [TA-54]. This facility is scheduled to have a fully implemented quality program by March, 1995, when the required training is scheduled to be complete.

Plutonium Facility (PF-4) [TA-55]. This facility can be in full compliance by June, 1996. The SOPs, the safety review procedures, and the existing quality programs are adequate to assure the safe operation of this facility at this time. A quality assurance training program to the requirements of 10CFR 830.120 was started this week and will continue. Additional efforts are being expended by ESH-14 to assist the management of the facility to implement the quality program for the entire facility.

To a large extent most of the program elements are in place for these facilities. The prevalent reason for not presently being in compliance is that additional training is required.

The process to determine the implementation status of these facilities was that of using the checklist provided in the Quality Assurance Guidebook for 5700.6C. This process involved reviewing each of the ten criterion and determining if procedures were in place for those requirements. If the procedures were existing it was determined the degree to which they have been implemented. To document the implementation status the following definitions were used:

IMPLEMENTED or (fully implemented)

The process, plans or procedures, are in place and being used which provides assurance that the desired product or results will be obtained. For example, calibration; a plan exists and is being used as evidenced by the existence of calibrated equipment, recall lists, and files providing evidence of repeated calibrations. If all of the calibration stickers have yesterday's date I would not accept that as evidence of implementation. Or, training; if a method exists which provides for training of personnel and there is documented proof that it is and has been used, I would say that it is implemented. The fact that it is going through a change would not affect that however, I would expect to verify the implementation of the change in the near future. If a procedure exists but there is no evidence of training to that procedure, it is not implemented.

PARTIAL IMPLEMENTATION

On the same track, if a training procedure required the training of all personnel before beginning an activity and less than 100% of the people were trained than they have only partial implementation for that facility. However, if the requirements are that a training program be in place with training needs determined for individuals and that training is scheduled, you may find that training has not been completed however the program could still be considered to be implemented.

In keeping with the spirit of the rule and Section 1 and 4 of the Implementation Guide, this was a management process. Management of these facilities determined the degree of implementation, and the decisions are theirs.

This is a departure from traditional quality assurance methodologies whereby the quality assurance organization would have conducted a formal audit to determine the degree of implementation. Audits have been conducted at the facilities in the past by various parties and audits are scheduled for the future. As requested by the reviewers, these reports will be made available.

Attached is the list of nuclear facilities received 11/30/94. Immediately following the acronym "LANL" the facilities have been numbered 1-54. The following action items are numbered to correspond to those numbers.

1. The "Arms Control Verification Facility" is listed. As near as we can determine, this was an operation once housed at TA-18. It has not been active for some time and is no longer existent.

2. In accordance with paragraph 830.3 of 10 CFR 830.120, Transportation is specifically excluded from the requirements of 10 CFR 830.120.

3. A letter certifying that all inventory of material has been removed will be or has been transmitted to the Performance Assessment Branch of the Operations Management Division of Albuquerque DOE.

4-11 These facilities are all within the CMR building and are covered by the Quality Plan submitted for that facility.

12,13, & 15. These facilities and or operations are under the direction of ESH-4 and are currently under their previously established Quality Plan. That plan after any revision necessary to address 10 CFR 830.120, will be submitted by April, 1995.

14. Should be completed by July, 1995. For the interim all work is conducted in accordance with approved SOP's and in some instances, test plans.

16. These facilities only become nuclear facilities when materials are brought into them for radiography. The procedures for the movement and safeguard of the materials will adequately cover the methods necessary to ensure the safety of the operation.

17 & 18. It is the position of the DX Division Office that these are not nuclear facilities but radiographic or X-ray machines. If, through resolution through the University Contract Office, these facilities should be determined to be classified as nuclear facilities a Quality Plan and implementation plan will be provided within 180 days of the determination. The Phermex facility is operated in accordance with test plans and SOPs for weapons related activities.

19 & 20 Previously addressed

21-29 These are all included within the submittal for TA-18

30. This facility is scheduled for decontamination and demolition commencing in July of 1995. The plan will be submitted prior to then. Until such time the facility is not accessible except to those who require access for purposes of planning the D&D. The material in the facility which categorizes this as a facility is oxides which have been trapped in the ductwork and filter systems.

31. Plan is in current submittal

32. A letter certifying that all inventory will be removed by March, 1995 has been or will be transmitted to the Performance Assessment Branch of the Operations Management Division, Albuquerque DOE.

33 & 34. Scheduled for submittal by January 1997, concurrent with the SAR. This schedule will be revisited during the next ninety days and revised as appropriate. In the interim, to ensure safe storage and handling of materials the following measures are being taken: SOPs are in place and utilized for the handling and storage of the materials. These include leak testing. The materials are stored in DOT type B shipping containers while not in use.

35. There are two sources stored in this facility. Both sources are stored in DOT type B shipping containers. Per attachment 1 of DOE STD 1027-92, "...material stored in DOT type B shipping containers (with or without overpack) may also be excluded from summation of a facility's radioactive inventory." It is the Laboratory's position that this is not a nuclear facility.

36. A letter certifying that all inventory will be removed by January, 1995 has been or will be transmitted to the Performance Assessment Branch of the Operations Management Division, Albuquerque DOE.

37. The QA Plan is currently in draft. There are tentative plans to remove the inventory. If this is not done the plan will be submitted by July, 1995. The SOPs for the conduct of operations for this facility are adequate to assure the safe operation for this time period.

38-40. Covered by the current submittal for TA-55

41-43. A "WASTE MANAGEMENT FACILITIES QUALITY MANAGEMENT PROGRAM" was in the development process at the time of our first transmittal of this plan. It became effective on December 22, 1994. It is included as part of our resubmittal.

44. This facility is approximately 15 months away from design and is currently out of operation. A qa plan has been drafted and is in a review and revision process. It will be submitted at least six months prior to start of design.

45. This is covered by the original submittal and also is now under the requirements of the waste management facilities quality management plan as are 41-43.

46. This is the compactor building which is non-operational. If it should go operational it would be under the current QA plan for TA-54.

47. QA plan in draft, will submit minimum of six months prior to operation. This facility is not operational and will not be until the SAR and quality plan are approved.

48. Covered by the current plan for TA-54

49. The mission of this facility has changed and the quantities of material in the building are below that which constitutes a nuclear facility per STD 1027. A letter to that effect should be transmitted by June 1995.

50-53. Covered by current TA-54 submittal

54-57. Construction scheduled to begin in the year 2003. QA plan will be submitted at least six months prior to beginning design (approximate start date is April, 1996).

This list as presented remains subject to review and agreement by the University of California which may revise some of these planned actions.

The activities/actions required to implement this plan are described in the institution wide quality plan and the implementation plans for the nine facilities submitted with this implementation plan. For the other facilities identified we will maintain a core group of people who will work with the management of those facilities to help meet the required dates. A milestone schedule will be developed to track both the commitments within the existing implementation plans as well as track the progress towards the submittal dates. We

recognize that the dates submitted herein for implementation are in many cases, unacceptably extended. Due to the time constraints we, in development of this plan, had to make some assumptions and tried not to present dates which we knew could not be met. As we proceed with this process all of the given dates will be reexamined and to the extent possible will be brought into a more realistic time frame. For the initial nine facilities for which we have submitted implementation plans two of them, the CMR and TA-55, are currently being reevaluated and new implementation plans will be submitted within ninety days of approval of this plan.

At such time as the facility management feels that they are fully implemented an independent audit will be performed to verify the implementation status.

The implementation of the plan within the facilities also requires a cooperative effort among many support groups. The radiation protection and dosimetery are provided by ESH Division personnel. The vendor evaluation and inspection and the receipt inspection may be provided by BUS-5 operations. Work performed by Johnson Controls (JCI) is under the direction of their quality assurance plan. For nuclear facilities the plans will have to be in accordance with the facility plans. For all activities except JCI these plans are prepared by ESH-14 personnel and approved by them so the controls exist. For the support contract (JCI), the statement of work is being revised to require their plans to be approved by the facility for which they are working. Another effort of support is being performed by our Facility Security and Safeguards Division. This is primarily in the area of construction and facility upgrade. They have a quality program being prepared with the assistance of the ESH-14 personnel and is consistent with the requirements of this Quality Management Plan. All safety related work performed within the facility or any work performed outside the facility that could impact the safety of that facility will be performed in accordance with the requirements of the facility quality plan. This may be accomplished in different manners. The agency supplying the support effort may have their plan approved by the facility management or they may elect to work to the existing facility plan. For vendors supplying work or materials, they would be evaluated for their ability to meet the facility requirements and then audited to evaluate their performance to the plan requirements.

These actions are based upon current budgeted amounts with the assumption that the approved budget allowance for the time period will be available. Any change in budget allocations may impact the scheduled dates thereby requiring a revised schedule and implementation plan.